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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,444	09/11/2003	Andrzej Chanduszeko	10983.0007.00000	4893
22852	7590	06/01/2010		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			06/01/2010 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/660,444

**Applicant(s)**

CHANDUSZKO ET AL.

**Examiner**

DIANE YABUT

**Art Unit**

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31, 34-37, 40-42 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31, 34-37, 40-42 and 60-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to applicant's amendment received on 2/23/2010.

#### ***Response to Arguments***

1. Applicant's arguments filed 2/23/2010 have been fully considered but they are not persuasive.
2. The applicant generally argues that the flexible arms **28, 30** of the device of Nobles would not be capable of traversing the oblique tunnel of the patent foramen ovale (PFO) since the device of Nobles is instead used in a defect **26** that is coplanar with the surface of tissue **22**. As mentioned below, Nobles discloses the device can be used in a "patent foramen ovale" (paragraph 141) and that each arm may extend from the device housing "in an asymmetric configuration wherein each arm 28, 30 has a different angle with respect to the axis of the housing 24" (paragraph 142), and therefore the device is suitable for traversing the oblique tunnel of the PFO.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 31, 34-35, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**).

Nobles discloses introducing into a heart of a patient a delivery member comprising at least a first flexible ("resilient") member **50** or **128** having a first end portion and arms **28** and **32** (first and second flexible members) at a second free end portion, and introducing said second free end portion through the opening of a patent foramen ovale **26** (page 6, paragraph 141) by entering the opening from one side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the opposite side prior to introducing a hole through a septal tissue **22**, contacting said first and second flexible members **28**, **32** on the opposite side of the septal tissue (Figure 4B), introducing a hole through the septal tissue from the one side to the opposite of the septal tissue, withdrawing said second free end portion of said flexible member from the opposite side (Figures 1-2, 15-16, 34-39). The hole may be introduced through the septal tissue while simultaneously biasing said second free end portion in contact with the tissue to minimize movement, as in Figures 79-80, 103A, in order to "provide mechanical support" to the tissue (paragraph 146). Nobles also discloses an apparatus ("patch") for joining tissue page 25, paragraph 351). After withdrawing the second free end portion of said flexible member, an occlusion device **880** or **890** may be introduced through the hole created by the septal tissue (paragraphs 314-320, Figures 72-73).

Although the flexible member is not spiral-shaped, it would have been obvious to one of ordinary skill in the art to modify Nobles with a spiral-shaped flexible member since coils, spirals, and helical configurations are well known shapes for elements that effectively approximate tissue.

Nobles discloses the claimed invention except for expressly disclosing introducing the delivery member from the right atrial side to a left atrial side, instead of from generally "one side" to the "opposite side" of septal tissue.

Ginn teaches delivering a delivery member to a patent foramen ovale from a right atrial side to the left atrial side (Figures 5A-8B; col. 7, line 60 to col. 8, line 9).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Nobles by introducing the delivery member from the right atrial side to a left atrial side, as taught by Ginn, since it was well known in the art for septal occluders to be effectively introduced percutaneously into a peripheral vein, such as a femoral or jugular vein, to be advanced through the vena cava into the right atrium and then advanced beyond the septum wall in the left atrium.

3. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**), as applied to claim 35 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Neither Nobles nor Ginn expressly discloses using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles and Ginn in order to more effectively ensure a tight occlusion of the PFO defect.

4. Claims 37 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**).

Nobles and Ginn disclose the claimed invention, as discussed in paragraph 3 above, except for the flexible members being hexagonally shaped.

Das teaches a closure method and a septal closure device and method using flexible members **24C** being introduced into a patent foramen ovale, which are hexagonally shaped (Figure 5C).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Nobles with Das, since the hexagonally shaped members provide bends which permit the frame to be collapsed more readily into a delivery catheter (col. 5, line 54 to col. 6, line 6).

5. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nobles** (U.S. Pub. No. **2002/0045908**) in view of **Ginn** (U.S. Patent No. **6,702,835**) and **Das** (U.S. Patent No. **5,334,217**), as applied to claim 41 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Nobles, Ginn, and Das do not expressly disclose using a tissue welding apparatus. However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Nobles, Ginn, and Das in order to more effectively ensure a tight occlusion of the PFO defect.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734